REMARKS

This paper responds to an Advisory Action mailed July 17, 2007 in the above-captioned application. Claims 1, 4-7, 9-23, 25-27, 32-43, 45-55, 61-70 and 72-86 were pending in this application when a Final Office Action was mailed on May 4, 2007. Applicants' claim amendments, filed on July 5, 2007 in response to the May 4, 2007 Final Office Action, were entered. Accordingly, claims 1, 4-7, 9-23, 25-27, 32-43, 45-55, 61-70, 72-76 and 78-86 are currently pending.

The status of the application in light of the July 17, 2007 Advisory Action is as follows:

(A) Claims 19, 20, 22, 23, 25-27, 32, 35-39, 78, 79, and 86 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,938,688 to Schiff ("Schiff") in view of Patent Application Publication US2002/0087201 to Firlik et al. ("Firlik '201") and Patent Application Publication US2002/0091419 to Firlik et al. ("Firlik '419");

(B) Claims 1, 4-7, 9-12, 14-18, 21, 40-43, 45-47, 49-55, 61-70, 72, 73, 75, 76, 80, 81, and 83-85 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Schiff in view of Firlik '419 and Firlik '201 and further in view of US 2004/0082847 to McDermott ("McDermott") and an article by Jeffrey Binder, titled "Functional Magnetic Resonance Imaging: Language Mapping," (Neurosurgery Clinics of North America) 8.3:383-392 (1997) ("Binder");

(C) Claims 13 and 48 stand objected to as being dependent upon a rejected claim, but are indicated to be allowable if rewritten to be in independent form; and

(D) Claims 74 and 82 are allowed.

A. Response to the Section 103 Rejections on the Basis of Schiff, Firlik '419 and Firlik '201

Claims 19, 20, 22, 23, 25-27, 32, 35-39, 78, 79 and 86 were rejected under 35 U.S.C. § 103 as being unpatentable over Schiff in view of Firlik '419 and Firlik '201. As

applicants stated in response to the Final Office Action, the combination of Schiff with Firlik '419 and/or Firlik '201 fails to establish a *prima facie* basis for rejecting claim 19 for at least the reason that Schiff expressly teaches away from elements of this claim. For example, Schiff expressly identifies the intralaminar nuclei, as opposed to any other region of the brain, as the preferred targets for electrical stimulation, stating that "[p]referably, the electrical stimulation is applied only to the patient's intralaminar nuclei or a portion thereof, without stimulating other regions of the patient's brain (Schiff at column 11, lines 32-34, emphasis added). Schiff repeatedly underscores the importance of stimulating the intralaminar nuclei, as opposed to a stimulation site "proximate to the dura mater and outside cortical surface of the patient's brain," as is expressly included in claim 19.

In the July 17, 2007 Advisory Action, the Examiner states that "Firlik '419 and Firlik '201 both expressly disclose and teach that it is well known in the art of electrical brain stimulation to choose a stimulation site for electrode implantation that is proximate the dura mater and outside a cortical surface of a patient's brain in order to provide a less invasive means for effecting not only cortical stimulation, but deep brain stimulation as well, in order to effectively treat a patient having impaired cognitive function." In other words, the Examiner's position appears to be that Firlik '419 and Firlik '201 disclose cortical stimulation as an equivalent or substitute for deep brain stimulation, and that this equivalency overcomes Schiff's clear teaching away from selecting a stimulation site within the patient's skull, proximate the dura mater and "outside a cortical surface of the patient's brain."

Firlik '419 and Firlik '201 do not disclose equivalency between cortical stimulation and deep brain stimulation. Applicants acknowledge that Firlik '419 and Firlik '201 disclose both cortical and deep brain stimulation. For example, Firlik '419 at page 4, paragraph 61, states that "several embodiments of devices for stimulating the cortical and/or deep-brain regions of the brain are described with reference to Figs. 6-40." This does not mean that cortical stimulation and deep brain stimulation are equivalent and/or directly or easily interchangeable. It simply means that embodiments of devices for stimulating cortical and/or deep brain regions are described in Figs. 6-40. It is clear that much of the

disclosure contained in Figures 6-40 and the associated text is directed to cortical surface electrodes, and that deep brain stimulation is limited to only particular embodiments. For example, Figure 24 explicitly discloses a pin 2360 having a length that is greater than the thickness of the cortex 709 to conduct electrical pulses to a portion of the brain below the cortex 709, "such as a deep brain region 710" (Firlik '419 at Figure 24 and paragraph 0126). But merely disclosing different embodiments, some of which may include cortical stimulation and some of which may include deep brain stimulation, in no way establishes an equivalency between such embodiments.

Both Firlik '419 and Firlik '201 disclose that cortical stimulation techniques may be less invasive than deep brain stimulation techniques, but again this disclosure in no way suggests that the two techniques are equivalent or interchangeable, or even that cortical stimulation operates on the brain via a mechanism that is the same as or equivalent to deep brain stimulation. Thus, the following statement by the Examiner is simply not true: "it would have been obvious to one having ordinary skill in the art at the time the invention was [made] to modify the method of Schiff such that the stimulation site is located proximate the dura mater, and outside a cortical surface of the brain, since such a modification would provide a means for selectively effecting deep brain stimulation without inducing serious complications from a highly invasive procedure, as taught by Firlik '419 and Firlik '201." The passages in Firlik '419 cited by the Examiner (pages 1-3, paragraphs 6-18) in support of this position discuss the prior art, including transcranial electrical stimulation, deep brain stimulation, and cortical surface stimulation, but nowhere suggest that cortical surface stimulation and deep brain stimulation are equivalent or produce equivalent results.

For at least the foregoing reasons, Schiff and other references describing deep brain stimulation do not establish equivalency between deep brain stimulation and cortical stimulation, and the Firlik references do not contradict the prior art in this regard. As further evidence that the two techniques are not equivalent, please refer to the attached Declaration of Justin Hulvershorn Under 37 C.F.R. Section 1.132, and the attached Declaration of Allen Wyler Under 37 C.F.R. Section 1.132.

The Examiner further states that the proposed modification (e.g., modifying Schiff's deep brain stimulation of the intralaminar nuclei to include Firlik's cortical stimulation) does not render the prior art unsatisfactory for its intended purpose or change its principal of operation. In fact, based upon Schiff's disclosure, the proposed modification does change Schiff's principle of operation. For example, Schiff states at column 13, lines 24-33 that

> [it] is believed that the intralaminar nuclei's role in supporting these function[s] relates to the generation of event-holding functions that may promote interaction across the cortex, possibly by enhancing synchronization, as described in Purpura. One theory of the present invention is that similar event-holding functions tied to head, hand, trunk or other bodily coordinates are generated by intralaminar nuclei stimulation and account for the improved cognitive function seen in patient's who are externally or internally stimulated.

Schiff goes on to say at column 15, lines 19-24 that

> The result of intralaminar nuclei stimulation under one aspect of the present invention is that correction of functional disconnections of brain regions by release of inhibition of remaining cortical or sub-cortical regions may be achieved by stimulation of the appropriately connected intralaminar nuclei; such release of inhibition may increase metabolic activity in suppressed areas.

Schiff states in addition at column 15, lines 24-34 that

> Alternatively, such stimulation may result in an alteration of population activity of many neurons in a local cortical area that improves information transfer or processing capabilities of the neurons in that region ... Under another aspect of the present invention, synchronization of stimulated areas may facilitate a broader integration of cortical processing via synchronization of activity within

the intralaminar nuclei of each thalamus and promote a global integrative process at the level of the cortex.

All the foregoing mechanisms for achieving Schiff's proported cognitive functioning improvement rely on stimulation of the intralaminar nuclei, and neither in Schiff nor in either of the Firlik references is there a suggestion that directly stimulating the cortex can produce an improvement in cognitive functioning that is within Schiff's principal of operation. Accordingly, (a) Schiff fails to disclose or suggest at least one feature of the pending claims, (b) Schiff expressly teaches away from the features of the pending claims, (c) Firlik '419 and Firlik '201 do not establish an equivalency between Schiff's methods and the claimed features, and (d) modifying Schiff's stimulation of the intralaminar nuclei to instead include "selecting a stimulation site within the patient's skull, proximate the dura mater and outside a cortical surface of the patient's brain," would clearly change Schiff's principal of operation. Therefore, for at least the foregoing reasons, the Section 103 rejections of the pending claims should be withdrawn.

Claims 20, 22, 23, 25-27, 32 and 35-39 depend from claim 19. Independent claims 78, 79 and 86 include features generally analogous to those discussed above with respect to claim 19. Accordingly, for at least the foregoing reasons and for the additional features of these claims, the Section 103 rejections of the foregoing claims should be withdrawn.

B. Response to the Section 103 Rejections on the Basis of Schiff, Firlik '419, Firlik '201, Binder and McDermott

Independent claims 1, 40, 61, 72-76, and 80-85 all include features generally analogous to those discussed above with reference to claim 19. Binder and McDermott fail to cure the deficiencies described above with reference to Schiff, Firlik '419 and Firlik '201 as establishing a *prima facie* basis for rejecting claim 19, and therefore, the foregoing independent claims as well. Claims 4-7, 9-12, 14-18, 21, 41-43, 45-47, 49-55, and 62-70 all depend from one of the foregoing independent claims. Accordingly, the Section 103 rejections of the foregoing independent and dependent claims should be withdrawn for at least the foregoing reasons and for the additional features of these claims.

C. Conclusion

The foregoing remarks addressing Firlik '419 and Firlik '201 are directed only to the disclosures of these applications, and not to the claims that have issued in these applications, or that may issue in applications claiming priority to these applications. Such claims may well encompass embodiments not specifically disclosed in these applications.

In light of the foregoing remarks, applicant's attorney respectfully requests reconsideration and allowance of all the pending claims. If the Examiner notices any informalities or other matters that may be expediently handled by telephone, she is encouraged to contact the undersigned attorney by telephone to resolve such matters.

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Respectfully submitted,

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